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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,843	12/10/2003	Chris Cicenas	END-5007NP	6679

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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/732,843

Applicant(s)

CICENAS ET AL.

Examiner

Helen Nguyen

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/19/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-3, 7, 9-13, 17-20** are rejected under 35 U.S.C. 102(b) as being anticipated by Gregoire et al (US Pat No. 5944673). In regards to **Claim 1**, Gregoire et al disclose a biopsy device comprising of a hollow biopsy needle or "piercing needle" (51) having a tissue receiving port (55), a hollow cutter (60) advanceable within the biopsy needle to sever tissue received within the tissue receiving port, and a sample tube or "tissue extractor" (65) having an open distal end, the sample tube supported on the biopsy device and advanceable within the cutter (Figure 2).

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4. In regards to **Claim 2**, Gregoire et al disclose the sample tube releaseably coupled to the biopsy device as shown in Figure 12 (Col.7, line 2). In regards **Claim 3**, Gregoire et al disclose a vacuum source (86) in communication with the sample tube (65) (Col.9, line 8-10). In regards to **Claim 7**, Gregoire et al disclose an apparatus for advancing and retracting the cutter within the biopsy needle. Specifically, Gregoire et al disclose a “cutter advance fork” (33) to move the cutter proximally and distally (Col.6, line 56-65).

5. In regards to **Claim 9**, Gregoire et al disclose the hollow needle comprising a lateral tissue receiving port (55) spaced from the distal end of the needle (Figure 2). In regards to **Claim 10**, Gregoire et al disclose the sample tube or tissue extractor comprising a vacuum lumen and a sample lumen. In particular, vacuum lumen is defined as the “extractor channel” (76) and the sample lumen is defined as the “tissue receptacle” (70). In regards to **Claim 11**, Gregoire et al disclose the sample tube comprising a tube wall feature for retaining tissue samples, specifically, a “tissue receptacle” (70).

6. In regards to **Claim 12**, Gregoire et al disclose the tube wall feature comprising a notch or tissue receptacle (70) disposed adjacent the distal end of the sample tube (Col.7, line 4-6). In regards to **Claim 13**, Gregoire et al disclose a rotating journal for rotating and advancing the cutter. The rotating journal is defined as the “driver gear” (34) and “cutter advance knob” (32), both of which must rotate to rotate and advance the cutter, respectively (Col.6, line 10-12, 63-65).

7. In regards to **Claim 17**, Gregoire et al disclose a method of obtaining a tissue sample comprising the steps of drawing tissue into a tissue receiving port (55) of a hollow biopsy needle (51), advancing a hollow cutter (60) in the needle to sever a tissue sample, and advancing a

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hollow sample tube (65) in the cutter to position the tissue sample in the sample tube.

Specifically, Gregoire et al disclose drawing tissue into the receiving port of the needle with the cutter in the second position (proximal) and then advancing the hollow cutter to sever the tissue sample (Col.11, line 12-16). The hollow sample tube is then advanced in the cutter, wherein advancement is defined as rotational movement of the tube to expose a different lateral tissue receiving port of the needle, to position an additional tissue sample for sampling (Col.11, line 7-10).

8. In regards to **Claim 18**, Gregoire et al disclose a method of stacking multiple samples within the sample tube (65). Specifically, because the biopsy instrument is used for extracting at least one tissue sample (Col.3, line 13), and because the sample tube (65) is hollow, thus allowing containment of samples within the lumen, it is obvious that multiple samples are stacked within the sample tube. After the removal of one tissue sample, additional tissue samples are collected either using the same tissue port or a different port (55) for removal of samples around the circumference of the needle (51) (Col.9, line 65-67). Application of vacuum through the extractor channel (76) of the sample tube draws the first tissue sample proximally, away from the distal tissue receptacle (70), allowing space for removal of the subsequent sample, which will also be displaced proximally within the same sample tube by vacuum, thus constituting stacking of multiple samples obtained in sequence (Col.11, line 38-41).

9. In regards to **Claim 19**, Gregoire et al disclose a method comprising providing a vacuum (86) through the sample tube (65) (Col.9, line 8-10). In regards to **Claim 20**, Gregoire et al disclose a method comprising providing axial vacuum in the cutter with at least one sample disposed. Gregoire et al disclose a vacuum (86) through the sample tube (65), which is inserted

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into the cutter (60), thus essentially providing vacuum in the cutter. Because the biopsy device is used for removing at least one tissue sample (Col.3, line 13), Gregoire et al disclose a method of providing a vacuum in the cutter with at least one sample disposed in the sample tube

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 4-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al in view of Bates et al (US Pat No. 6273861). In regards to **Claim 4**, Gregoire et al disclose a biopsy device comprising of a sample tube or “tissue extractor” (65) but do not disclose a fluid method of advancing the tissue extractor. Bates et al disclose a source of compressed fluid as an advantageous means of advancing a tissue excising means of a tissue sampling device (Col.8, line 27-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to advance the sample tube of Gregoire et al using fluid pressure, as taught by Bates et al, to further automate the biopsy device and obtain the benefits associated with using fluid pressure.

12. In regards to **Claim 5**, Gregoire et al disclose a sample tube or “tissue extractor” (65) but do not disclose a pneumatic means of advancing the tissue extractor. Bates et al disclose a pneumatically operated tissue sampling device to impart the advantages of automating a biopsy device using compressed gas (Col.10, line 32-33). Therefore, it would have been obvious to one

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of ordinary skill in the art at the time the invention was made to advance the sample tube of Gregoire et al pneumatically, as taught by Bates et al, to further automate the biopsy device and obtain the benefits associated with using compressed gas.

13. In regards to **Claim 6**, Gregoire et al disclose a sample tube of “tissue extractor” (65) but do not disclose a piston operatively associated with the tube. Bates et al disclose a stylet piston (290) and cannula piston (307) using compressed fluid to provide the necessary force to automatically drive the sampling device (Col.15, line 43-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a piston, as taught by Bates et al, operatively associated with the sample tube of Gregoire et al, to similarly automate the sample tube of the biopsy device and obtain the associated benefits.

14. **Claims 8 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al in view of Burbank et al (US Pat No. 5526822). In regards to **Claim 8**, Gregoire et al disclose a sample tube or “tissue extractor” (65) but do not disclose an apparatus for advancing and retracting the extractor within the cutter. Burbank et al disclose a “tubular knock out pin linear driver” (112) supplying linear motion to automate the sample tube, referred to as “tubular knock out pin” (92) (Col.14, line 40-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an apparatus for advancing and retracting the sample tube of Gregoire et al, as taught by Burbank et al, to fully automate the biopsy device as automation decreases trauma and increases the consistency and quantity of tissue samples (Col.4, line 40-43).

15. In regards to **Claim 16**, Gregoire et al disclose a biopsy device comprising of a hollow biopsy needle or “piercing needle” (51) having a lateral tissue receiving port (55), a hollow cutter

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(60) advanceable within the biopsy needle to sever tissue received within the tissue receiving port, a sample tube or "tissue extractor" (65) having an open distal end and a distal end in communication with a source of vacuum (75, Col.7 line 28-29), the sample tube releaseably supported on the biopsy device and advanceable within the cutter, and a drive mechanism for advancing (32) and rotating (34) the cutter within the biopsy needle. However, Gregoire et al do not disclose the drive mechanism comprising an internally threaded, rotatably driven component. Burbank et al disclose an internally threaded, rotatably driven component for advancing and rotating the cutter, referred to as "cannular inner cutter collet" (762) (Col.19, line 49-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a drive mechanism using internal threads as taught by Burbank et al, into the drive mechanism used by Gregoire et al, to provide an optimal method of automating the cutter.

16. **Claims 14-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al in view of Tsonton et al (US Pat No. 2004/0077972). Gregoire et al disclose a cutter (60) but do not disclose the cutter having at least one hole extending through an outer surface of the cutter and spaced from a distal end. Tsonton et al disclose a biopsy probe including a stylet with radially-oriented through holes near the distal end to maintain fluid communication between the vacuum lumen chamber (64) and the cutter lumen (56) (§ 0078). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cutter of Gregoire et al to include at least one or a plurality of holes extending through the cutter and spaced from the distal end, as taught by Tsonton et al, to maintain fluid vacuum communication between the various lumens (Figure 7).

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17. **Claims 18 and 20** are also rejected under 35 U.S.C. 103(a) as being unpatentable over Gregoire et al in view of Chin et al (US Pat No. 5195533). In regards to **Claim 18**, Gregoire et al disclose a method of obtaining tissue samples within a sample tube but do not specifically disclose stacking multiple samples. Chin et al disclose stacking multiple samples within the same biopsy needle for ease and efficiency of sampling (Col.2, line 28-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to integrate stacking multiple samples, as taught by Chin et al, into the tissue sampling method using a tissue sample tube disclosed by Gregoire et al, to provide a more atraumatic and efficient method of sampling.

18. In regards to **Claim 20**, Gregoire et al disclose providing axial vacuum in the cutter (as explained in the 102 rejection of **Claim 20**) but do not specifically disclose doing so with at least one sample disposed in the sample tube. Chin et al disclose stacking multiple samples for ease and efficiency of sampling (Col.2, line 28-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use vacuum, a necessary part of the tissue sampling process, as disclosed by Gregoire et al, while removing multiple samples for stacking, as taught by Chin et al, to provide a more atraumatic and efficient method of sampling.

Conclusion


19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HQN 1/4/06


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